UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,101	04/01/2005	Kristjan S Gudmundsson	PU4959USW	7560

23347 7590 07/05/2006

GLAXOSMITHKLINE
CORPORATE INTELLECTUAL PROPERTY, MAI B475
FIVE MOORE DR., PO BOX 13398
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER	
BALASUBRAMANIAN, VENKATARAMAN	
ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/530,101	Applicant(s) GUDMUNDSSON ET AL.	
	Examiner Venkataraman Balasubramanian	Art Unit 1624	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 June 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See attached Advisory Action*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Venkataraman Balasubramanian
Primary Examiner
Art Unit: 1624
6/29/06

ADVISORY ACTION

The applicants' response along with a declaration under 37 CFR 1.131, filed 6/22/2006 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered for the following reasons.

Applicants' response did not overcome following rejections made in the previous office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-16, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim and share the same limitation for reasons of record. To repeat:

1. 'Claim 14 is indefinite as it appears to be a pharmaceutical composition but does not recite any other ingredient. A composition claim should have more than one ingredient.

This rejection is same as made in the previous office action. Applicants' traversal is not persuasive.

First of all, a composition should have more than one ingredient. Claim 14 does not recite any other ingredient. Applicants are relying on the comprising language and

had argued that the composition can include besides a compound of formula 1, any ingredient at all. See response, page 10 first paragraph.

Recitation of the phrase " comprising" renders this claim indefinite as the term is open-ended and can include more than what is being positively recited therein. See MPEP 2111.03 which states: The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

Therefore, if one were accept applicants' assertion that this claim includes any other ingredients, then the claim 14 is to interpreted as "compound of claim 1 + any or all ingredients of the universe of composition". Granting this if one were to examine claim 15 and 16, it would appear that claim 15 would be "compound of claim 1 + any or all ingredients of the universe of composition + a pharmaceutically acceptable carrier or diluent" and claim 16 would be "compound of claim 1 + any or all ingredients of the universe of composition + an antiviral agent selected from the group consisting of acyclovir and valaciclovir or a pharmaceutically acceptable salt thereof". Thus it is clear

any or all ingredients of the universe of composition do not include a pharmaceutically acceptable carrier or diluent of claim 15 and an antiviral agent selected from the group consisting of acyclovir and valaciclovir or a pharmaceutically acceptable salt thereof of claim 16. Thus, it is not clear what is included and what is excluded by the term comprising in claim 14. Hence, claim 14 fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As for appeal, the case laws cited in the above passage is relied on along with the interpretation.'

This rejection is same as made in the previous office action and includes previous response to applicants' traversal.

Applicants' additional traversal in the current response, is also not persuasive. Applicants appear to confuse the issue as pertaining to "comprising".

First of all, the term "comprising" as agreed by the applicants is open. Therefore, it may include other ingredients or may not include other ingredients. If it did not include any other ingredient, the said claim would be indefinite, as a composition requires more than one ingredient.

Secondly, as noted above, if it were to include any or all ingredients, the said claim is complex composition containing more than one active ingredient, one of which being the compound of claim1. But claim 16 includes clearly additional active ingredient

Therefore, as recited it is not possible to know whether it is a complex composition or a simple one-active ingredient composition lacking additional inert ingredient.

Hence, this rejection is proper and is maintained.

2. The currently amended claim 19 is a duplicate of claim 17 as there is no material difference except for the wording between claim 17 and claim 19. If the scope of claim 19 is different from claim 17, then applicants should show what the difference is and indicate where in the specification the support for the different scope is provided.

This rejection same as made in the previous office action. Applicants' traversal is not persuasive. Applicants argued that page 22 provide what is the material difference between claim 17, which recites treating HSV-1 and HSV-2 infection and claim 18, which recites treating a condition or disease associated with HSV-1 and HSV-2 infection.

First of all, mode of action of instant compounds as stated in the specification relates treating the herpes viral infection not any or all disease. If the claim 18 is meant to recite treating any or all disease, then it will clearly raise 112 first paragraph scope of enablement issue.

Secondly, reading the limitation of specification into claim is improper. As directed by applicants, page 22, last two paragraphs read "the compounds of the invention are useful in the treatment or prophylaxis of conditions or diseases associated with herpes virus infections, particularly conditions or diseases associated with latent herpes virus infections in an animal, e.g., a mammal such as a human. By conditions or diseases associated with herpes viral infections is meant a condition or disease, excluding the viral infection per se, which results from the presence of the viral infection, such as chronic fatigue syndrome which is associated with EBV infection; and multiple

sclerosis which has been associated with herpes viral infections such as EBV and HHV-6. Further examples of such conditions or diseases are described in the background section above.

In addition to those conditions and diseases, the compounds of the present invention may also be used for the treatment or prophylaxis of cardiovascular diseases and conditions associated with herpes virus infections, in particular atherosclerosis coronary artery disease and restenosis and specifically restenosis following angioplasty RFA). Restenosis is the narrowing of the blood vessels which can occur after injury to the vessel wall, for example injury caused by balloon angioplasty or other surgical and/or diagnostic techniques, and is characterized by excessive proliferation of smooth muscle cells in the walls of the blood vessel treated. It is thought that in many patients suffering from restenosis following angioplasty (RFA), viral infection, particularly by CMV and/or HHV-6 plays a pivotal role in the proliferation of the..."

It is clear from these paragraph that applicants urging treating diseases and conditions which does not involve HSV infection including prophylaxis which is preventing such diseases. If these limitations were read into the claim, as urged by the applicants, then it would necessitate a 112 first paragraph scope enablement rejection.

Hence, this rejection is proper and is maintained.

3. Claim 20 is indefinite as it recites a process of preparing compound of formula I but limits the R^3 and R^4 choices. R^3 and R^4 choices do not match with those of claim 1. Note the R^3 and R^4 choices of claim 1 are broader than that of claim 20. Thus, it is not clear how one would arrive at compound of formula I recited in claim 1 from the process

of claim 20 with limited R^3 and R^4 choices to broader choices of R^3 and R^4 choices in claim 1.

This rejection is same as made in the previous office action. If the present amendment were entered, then this rejection would be obviated.

Allowable Subject Matter

Claim 13 is allowed. Claims 1-6, 9-12 and 17 are objected to, barring finding of any prior art in a subsequent search and deletion of a proviso at the last but one line of claim relating non-elected subject matter, would be allowable.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

Venkataraman Balasubramanian

6/29/2006